



**Department of Veterans Affairs
Northern California Health Care System**

Research Service

PRIVACY OFFICE REVIEW OF RESEARCH PROJECTS

Standard Operating Procedures (SOP)

R&D Approval Date: July 29, 2015

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1. PURPOSE

To identify the necessary steps in determining which research projects require a privacy review and the associated review process.

2. PRIVACY REVIEW REQUIREMENT FOR RESEARCH STUDIES

1. The following research studies are to be submitted to the Privacy Office for review:
 - a. All **NEW** human subjects' research studies.
 - b. All human subjects' research studies submitted as part of the **ANNUAL REVIEW OR AMENDMENT/MODIFICATION** process, **IF** the following conditions exist:
 - ✓ Changes in how VA data is used
 - ✓ Changes in how VA data is accessed
 - ✓ Changes in how VA data is disclosed
 - ✓ Changes to the HIPAA Authorization
 - ✓ Changes to or the application for a HIPAA Waiver
 - ✓ Changes to the Informed Consent that affects how the research uses, access, and discloses Veterans data

3. PROCEDURE

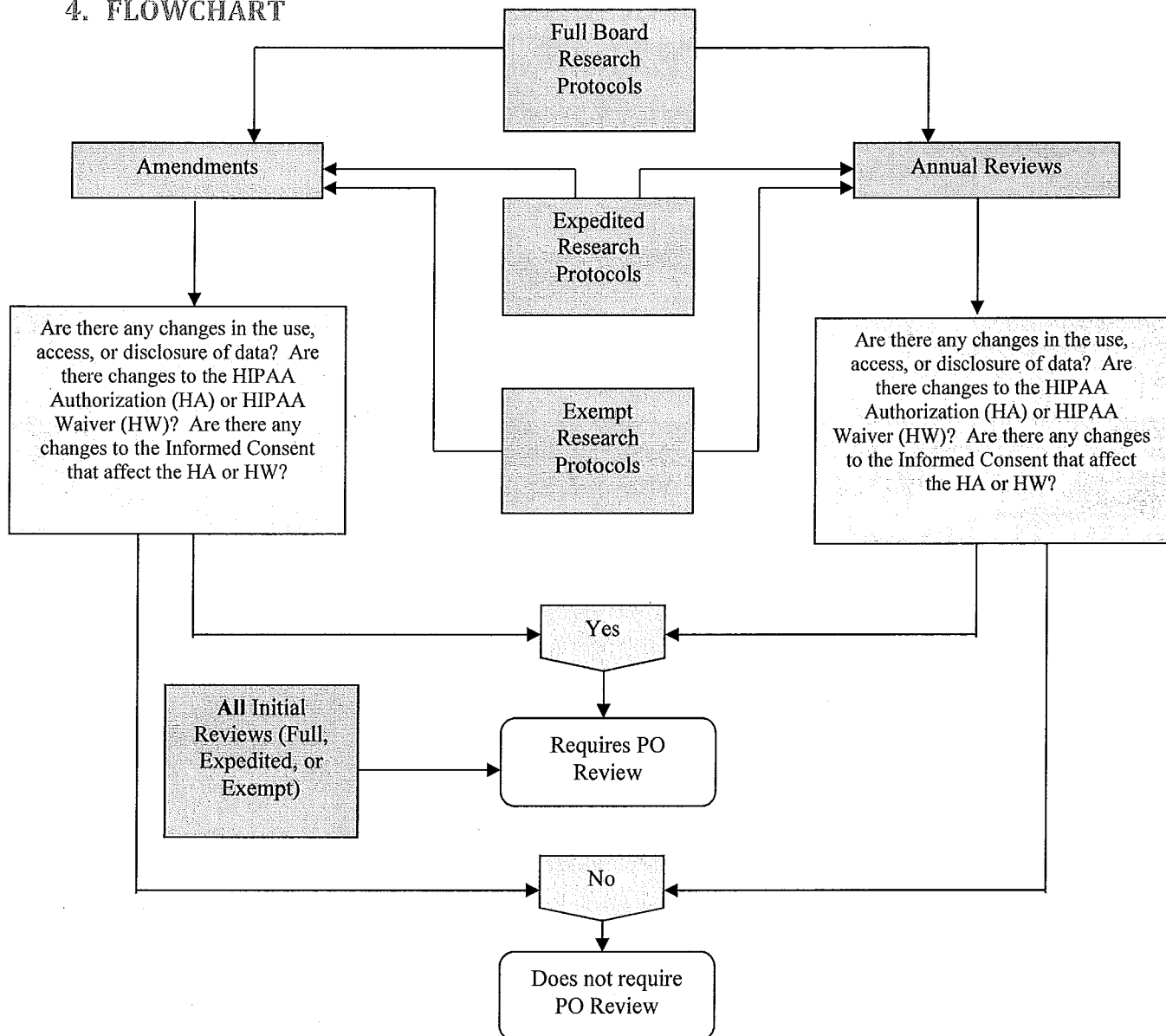
1. The IRB Administrator will provide email notification to the Privacy Officer (PO) upon electronic posting of completed research packets. The email will have a hyperlink to the documents to be reviewed.
 - a. Completed research packets requiring PO review will be placed in the following folder \\vhmacrchsmc\mac_research\RESEARCH_SERVICE\Gatekeeper\Reviews - ISO and PO\PO\PO Assigned Reviews. The IRB Administrator will create a study folder with the MIRB Number and PI's last name, in the "PO Assigned Reviews" folder.
 - b. The IRB Administrator will post a copy of the application packet and the MIRB reviewer notice for the application packet, in the "PO Assigned Reviews" folder, for the study.
 - c. The IRB Administrator will send email notification to the PO as stated above.
2. First PO Review
 - a. Full IRB Committee research studies requiring a privacy review will be submitted to the Privacy Officer a minimum of **15 business days** prior to the IRB meeting.
 - b. Expedited and Exempt studies requiring a privacy review will be submitted to the Privacy Officer a minimum of **15 business days** prior to the IRB meeting at which time they are presented on the IRB Agenda.
 - c. The PO will interact with the investigative team to finalize privacy requirements.

- d. The PO will complete the required review using the privacy checklist (Attachment A) and MIRB reviewer notice, within **8 business days** so that the IRB Administrator or designee can distribute the meeting materials to IRB members one week to 10 days prior to each meeting.
- e. If the PO determines that revisions are required the following process shall be used:
 - 1) The PO will contact the PI and/or Study Contact person listed on the first page of the application and CC Research Service at v21macresearchinbox@va.gov.
 - 2) The PO will communicate the problems identified during the PO review and provide instruction, guidance, and information needed to resolve the problem.
 - 3) The PI and/or Study Contact person will submit the revisions to Research Service and CC the PO.
 - i. If the revisions are not sent to the PO, Research Service will send a copy of the revised documents to the PO.
 - 4) The PO will review the revised documents and determine if the revisions are appropriate.
 - 5) The PO will communicate the determination in item 4 above to Research Service **within 2 business days**.
- f. Completed First PO reviews will be placed in the following folder \\vhamacrchsmc\mac_research\RESEARCH SERVICE\Gatekeeper\Reviews - ISO and PO\PO\PO Completed Reviews. The PO will create a study folder with the MIRB Number and PI's last name, in the "PO Completed Reviews" folder.
- g. The PO will post a signed copy of the privacy checklist and MIRB reviewer notice, in the "PO Completed Reviews" folder, for the study.
- h. The PO will send email notification to the IRB Administrator upon electronic posting of completed PO review. The email will have a hyperlink to the document containing the signed PO review.

3. Second/Final Privacy Officer

- a. Following final IRB Approval, the PO will review the Waiver of Authorization Determination Letter and complete the required review using the privacy checklist and MIRB reviewer notice.
- b. Completed Second/Final PO review will be placed in the following folder \\vhamacrchsmc\mac_research\RESEARCH SERVICE\Gatekeeper\Reviews - ISO and PO\PO\PO Completed Reviews.
- c. The PO will post a signed copy of the privacy checklist and MIRB reviewer notice, in the "PO Completed Reviews" folder, for the study, **within 2 business days**.
- d. The PO will send email notification to the IRB Administrator upon electronic posting of the completed PO review. The email will have a hyperlink to the document containing the finalized PO review.

4. FLOWCHART



5. REFERENCES:

2011 Local Accountability for Research Meeting/ORO & VHA Privacy; VHA Handbook 1605.

6. SIGNATURE BLOCK

A handwritten signature in black ink, appearing to read "Robert O'Donnell", written in a cursive style.

Robert O'Donnell, MD, PhD
Acting Associate Chief of Staff for Research

A handwritten signature in black ink, appearing to read "Paramita Ghosh", written in a cursive style.

Paramita Ghosh, PhD
Chair, Research and Development Committee